

On February 7, 2020, Dr. Kenneth Weeks, III performed a left hip arthroscopic labral repair and femoroplasty surgery on Plaintiff at the Charlotte Surgery Center. (DE 8 ¶10). Dr. Weeks used a drill manufactured by Defendant to complete the procedure. (*Id.* ¶¶18-19). Unbeknownst at the time, during the operation the drill bit broke while attempting to penetrate Plaintiff's acetabulum. (DE 8 at ¶11). Following the surgery, Plaintiff experienced pain and functional limitations in her left hip. (DE 8 at ¶15). Fluoroscopic images revealed that part of the drill bit had inadvertently broke off and implanted in Plaintiff's hip during surgery. (*Id.*). Dr. Weeks determined it was safer to leave the drill bit in Plaintiff's hip rather than remove it due to potential complications from another surgery. (*Id.*).

However, on March 13, 2020, Plaintiff ultimately underwent a second surgery to remove the broken drill bit because Plaintiff's hip failed to heal properly as the drill bit had migrated within Plaintiff's hip. Dr. John Masonis performed the second surgery. (*Id.*). As a result of the surgery to remove the drill bit, Plaintiff endured permanent injuries to her lateral femoral cutaneous nerve. (*Id.*). The injury was revealed after a nerve conduction study was performed on April 20, 2021. (*Id.*). On October 8, 2020, Defendant was notified that its drill bit had implanted in Plaintiff's hip. Defendant identified the implanted drill bit as "Product Number UNKN04402700." (*Id.* at ¶18).

Plaintiff alleges that Defendant made affirmations regarding the safety and reliability of the drill bit to her doctor. (*Id.* at ¶35). There are no facts that show Plaintiff knew of any representations made by Defendant regarding the drill bit prior to the surgery, nor are there any facts that show Plaintiff elected to undergo the surgery because of representations she learned about the drill bit.

B. Procedural Background

Plaintiff filed an action in Gaston County Superior Court on August 20, 2021. (DE 1 at ¶1).

On September 28, 2021, Defendant removed the case to the Western District Court of North Carolina. (DE 1). On November 16, 2021, Plaintiff filed an Amended Complaint with three claims: breach of the implied warranty of merchantability, breach of express warranty, and negligence. (DE 8). Defendant then moved to dismiss the Amended Complaint, arguing that the warranty claims fail as there is no contractual privity and that the negligence claim is inadequately pleaded. (DE 11).

The Magistrate Judge entered an M&R recommending that this Court grant in part Defendant's Motion to Dismiss as to the warranty claims and deny in part as to the negligence claim. (DE 15). Plaintiff objected to the M&R, arguing that the Amended Complaint states valid breach of warranty claims. (DE 16). While in agreement with the M&R's recommendation to dismiss the warranty claims, Defendant objects to the M&R's reasoning for doing so, arguing that it will improperly create an additional exception to North Carolina's strict contractual privity requirement. Defendant further objects to the M&R's finding that the negligence claim is properly pled. (DE 17).

II. STANDARD OF REVIEW

A district court may assign dispositive pretrial matters to a magistrate judge for "proposed findings of fact and recommendations." 28 U.S.C. § 636(b)(1)(B). The Federal Magistrate Act provides that a district court "shall make a de novo determination of those portions of the report or specific proposed findings or recommendations to which objection is made." *Id.* § 636(b)(1); *Camby v. Davis*, 718 F.2d 198, 199 (4th Cir. 1983). However, "when objections to strictly legal issues are raised and no factual issues are challenged, de novo review of the record may be dispensed with." *Orpiano v. Johnson*, 687 F.2d 44, 47 (4th Cir. 1982). De novo review is also not required "when a party makes general and conclusory objections that do not direct the court to a

specific error in the magistrate’s proposed findings and recommendations.” *Id.* Similarly, when no objection is filed, “a district court need not conduct a de novo review, but instead must ‘only satisfy itself that there is no clear error on the face of the record in order to accept the recommendation.’” *Diamond v. Colonial Life & Acc. Ins. Co.*, 416 F.3d 310, 315 (4th Cir. 2005) (quoting FED. R. CIV. P. 72, advisory committee note).

The standard of review for a motion to dismiss under Rule 12(b)(6) for failure to state a claim is well known. FED. R. CIV. P. 12(b)(6). “A motion to dismiss under Rule 12(b)(6) ‘challenges the legal sufficiency of a complaint,’ including whether it meets the pleading standard of Rule 8(a)(2).” *Fannie Mae v. Quicksilver LLC*, 155 F. Supp. 3d 535, 542 (M.D.N.C. 2015) (quoting *Francis v. Giacomelli*, 588 F.3d 186, 192 (4th Cir. 2009)). A complaint attacked by a Rule 12(b)(6) motion to dismiss will survive if it contains enough facts “to state a claim to relief that is plausible on its face.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Facial plausibility means allegations that allow the court to draw the reasonable inference that defendant is liable for the misconduct alleged. *Ashcroft v. Iqbal*, 556 U.S. 662, 663 (2009). “Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” *Id.* at 678.

Federal Rule of Civil Procedure 8(a)(2) requires only “a short and plain statement of the claim showing that the pleader is entitled to relief.” FED. R. CIV. P. 8(a)(2). Specific facts are not necessary; the statement need only “give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.” *Twombly*, 550 U.S. at 555. Additionally, when ruling on a motion to dismiss, a court must accept as true all of the factual allegations contained in the complaint. *Erickson v. Pardus*, 551 U.S. 89, 93–94 (2007). Nonetheless, a court is not bound to accept as true legal conclusions couched as factual allegations. *Papasan v. Allain*, 478 U.S. 265, 286 (1986).

“Courts cannot weigh the facts or assess the evidence at this stage, but a complaint entirely devoid of any facts supporting a given claim cannot proceed.” *Potomac Conference Corp. of Seventh-Day Adventists v. Takoma Acad. Alumni Ass’n, Inc.*, 2 F. Supp. 3d 758, 767–68 (D. Md. 2014). Furthermore, the court “should view the complaint in a light most favorable to the plaintiff.” *Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1134 (4th Cir. 1993).

III. DISCUSSION

A. Negligence Claim

Defendant argues the negligence claim does not meet the minimum pleading standard established in *Twombly* and *Iqbal* and, therefore, should be dismissed. After reviewing the Amended Complaint, the M&R found Plaintiff’s negligence claim was sufficiently pled. This Court agrees.

To find a defendant negligent, Plaintiff must show Defendant “owed Plaintiff a duty of reasonable care, (2) [Defendant] breached that duty, (3) [Defendant]’s breach was an actual and proximate cause of Plaintiff’s injury, and (4) Plaintiff suffered damages as the result of [Defendant]’s breach.” *Gibson v. Ussery*, 196 N.C. App. 140, 675 S.E.2d 666, 668 (2009). Additionally, Defendant, as a manufacturer, “must use reasonable care in the design and manufacture of products, and this includes the duty to perform ‘reasonable tests and inspections to discover latent hazards.’” *Nicholson v. Am. Safety Util. Corp.*, 124 N.C. App. 59, 65 (1996), *aff’d as modified*, 346 N.C. 767 (1997).

Assuming all the well pleaded facts are true, Plaintiff sufficiently addressed each element of her negligence claim to survive a 12(b)(6) challenge. Plaintiff alleged that “Defendant had a duty to exercise reasonable care in the design, manufacture, marketing, testing, approval, application for approval, inspection, sale and distribution of the surgical drill [sic] bit into the

stream of commerce,” and Defendant breached this duty when the drill bit broke in its ordinary use and implanted in Plaintiff’s hip during surgery. (DE 8 at ¶¶39–40). This aligns with North Carolina law which requires manufacturers to use reasonable care in designing products. *Nicholson*, 124 N.C. App. at 65. Accordingly, the failure of the drill bit during its normal operation could reasonably be seen as a breach of Defendant’s duty to Plaintiff—the patient.

Plaintiff further alleges that, as a result of the malfunctioning drill bit which implanted in her hip, she “experienced pain, discomfort, and emotional distress” resulting in permanent injury and “incurred medical expenses and lost earnings.” (DE 8 at ¶5). Plaintiff thus alleges sufficient facts that she was harmed by the malfunctioning drill bit.

Plaintiff also alleges sufficient facts to show that the malfunctioning drill bit was both a direct and proximate cause of her injuries as but-for the faulty drill bit Plaintiff’s harm would not have occurred, and it is not too farfetched for a drill bit that implants in a patient’s hip to cause harm to the patient. (DE 8 at ¶41). *Inge v. Seaboard Air Line Ry. Co.*, 192 N.C. 522 (1926) (quoting *Milwaukee & Saint Paul Ry. Co. v. Kellogg*, 94 U.S. 469, 475, (1876)) (explaining proximate cause); *Wright v. Lassiter*, 921 F.3d 413, 419 (4th Cir. 2019) (citing *Burrage v. United States*, 571 U.S. 204 (2014)) (“[F]actual causation (also sometimes called actual cause, causation-in-fact, and ‘but-for’ causation), [] requires a plaintiff to show that his injury would not have occurred but for the defendant’s conduct.”).

Therefore, assuming all the well pleaded facts in the complaint are true, Plaintiff alleged sufficient facts to overcome a motion to dismiss as to her negligence claim.

B. Warranty Claims

At issue is whether Plaintiff, as a patient, can bring breach of warranty claims against the manufacturer of a medical device that malfunctioned, resulting in a broken drill bit unintentionally

implanting in her. There is no dispute that Plaintiff was not aware of the drill or drill bit that was used during her surgery, nor did she elect to have the operation because of any representations of the manufacturer.

The M&R recommends dismissing the warranty claims for lack of privity. In particular, the M&R makes a distinction between a medical device that was intended to be implanted and the present case. Plaintiff objects to the M&R, arguing that North Carolina case law allows the end user to bring breach of warranty claims against the manufacturer of a faulty mechanical device. Defendant also objects, not with the M&R's recommendation of dismissing the breach of warranty claims, but with the M&R's distinction between intentionally implanted medical devices and non-intentionally implanted medical devices.

North Carolina recognizes claims for breach of express warranty and breach of the implied warranty of merchantability, both of which are at issue here. As to breach of express warranty, "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise." N.C. GEN. STAT. ANN. § 25-2-313(1)(a). As to breach of the implied warranty of merchantability, "a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." N.C. GEN. STAT. ANN. § 25-2-313(1)(a).

Generally, a plaintiff must have contractual privity with a defendant to bring a breach of warranty claim. *Atl. Coast Mech., Inc. v. Arcadis, Geraghty & Miller of N.C., Inc.*, 175 N.C. App. 339, 345 (2006); *Crews v. W.A. Brown & Son, Inc.*, 106 N.C. App. 324, 332 (1992); *Terry v. Double Cola Bottling Co.*, 263 N.C. 1, 2 (1964); *Thomason v. Ballard and Ballard Co.*, 208 N.C. 1, 4 (1935). However, North Carolina's version of the Uniform Commercial Code removes the

privity requirement in personal injury cases for express or implied warranties where the injured party is a “natural person who is in the family or household of his buyer or who is a guest in his home if it is reasonable to expect that such person may use, consume or be affected by the goods.” N.C. GEN. STAT. ANN. § 25–2–318. In other words, when the buyer is in privity of contract with the seller, any express or implied warranties made to the buyer inure to the benefit of the buyer’s family or household guests. Another statutory exception, under the North Carolina Products Liability Act, removes the privity requirement for “a buyer, as defined in the Uniform Commercial Code, of the product involved” where the buyer brings “a product liability action directly against the manufacturer of the product involved for breach of implied warranty.” N.C. GEN. STAT. ANN. § 99B–2. Thus, a buyer who is not in privity with the manufacturer can bring a breach of implied warranty claim, notwithstanding the lack of privity.

North Carolina courts also tend to uphold an exception for buyers who are not in privity with the manufacturer when the manufacturer intends its warranties to be conveyed to a buyer through the retailer. *Kinlaw v. Long Mfg. N. C., Inc.*, 298 N.C. 494, 499 (1979) (“[A] manufacturer can extend a warranty beyond the bounds of privity if he makes representations designed to induce a purchase and directed to the ultimate purchaser.”). This normally occurs when a manufacturer advertises, labels, or provides manuals with its products with the intention of inducing the ultimate purchaser to buy the product from a retailer. *Id.* at 500. For example, in *Kinlaw* the court removed the privity barrier when a buyer bought a tractor from a retailer, where the tractor came with a manual from the manufacturer warranting that the tractor would be free from defects. *Id.* at 496–500. Similarly, in *Alberti v. Manufactured Homes*, the North Carolina Supreme Court allowed breach of warranty claims against the manufacturer to survive when a buyer purchased a mobile home based on representations made by the retailer, when those representations were first given

from the manufacturer to the retailer for the purpose of inducing customers to buy the product. 329 N.C. 727, 729 (1991). Plaintiff relies on these two North Carolina Supreme Court cases, arguing that Defendant made representations to Plaintiff's doctor regarding the safety and reliability of the drill and that Plaintiff relied upon the judgment of her doctor in selecting the appropriate tools for her surgery.

There appears to be a split within the Fourth Circuit for district courts interpreting North Carolina law on whether an exception to the privity requirement applies for patients who have medical devices implanted. At least two cases have relied on Plaintiff's argument to hold that plaintiffs who have medical devices purposefully implanted, which turn out to be defective, can bring breach of warranty claims against the manufacturer even though there is no contractual privity between the manufacturer and the patient. In the Eastern District of North Carolina, Judge Boyle denied a motion to dismiss breach of express and implied warranties against a manufacturer when a patient, who was not in privity with the manufacturer, was implanted with a faulty pelvic mesh "because plaintiff plausibly alleged that she relied on her surgeon's medical judgment, which was formed by defendants' express warranties." *Resendez v. C. R. Bard, Inc.*, No. 5:19-CV-299-BO, 2020 WL 1916690, at *2 (E.D.N.C. Apr. 20, 2020). Likewise, in the Southern District of West Virginia, Judge Goodwin denied defendant-manufacturer's summary judgment on plaintiff-patient's warranty claims (in a case arising out of a multidistrict litigation) because, "[e]ven if Ms. Justus relied only on Dr. Howden's medical judgment in deciding to have the Prolift implanted, a reasonable juror could find that Ms. Justus relied on the express warranties of Ethicon as they were provided to Dr. Howden, which formed the basis for Dr. Howden's medical judgment." *Justus v. Ethicon, Inc.*, No. 2:12-CV-00956, 2016 WL 7404712, at *5 (S.D.W. Va. Dec. 21, 2016) (analyzed under North Carolina law).

However, in the Eastern District of North Carolina, Judge Flanagan dismissed a breach of implied warranty claim for an implanted medical device for lack of privity because the plaintiff was not considered a buyer of the implanted device under the Uniform Commercial Code. *Teague v. Johnson & Johnson, Inc.*, No. 5:21-CV-68-FL, 2022 WL 56526, at *6-7 (E.D.N.C. Jan. 5, 2022). In *Teague*, the court dismissed the breach of implied warranty claim because there were no facts showing the plaintiff was a buyer and “medical professionals do not engage in the sale of ‘goods.’” *Id.* at *7 (citing *Cameron v. New Hanover Mem’l Hosp., Inc.*, 58 N.C. App. 414, 445) (internal citations omitted). Thus, as there was no privity, and no exception to the privity requirement applied, the court dismissed the breach of implied warranty claim. *Id.*

While not analyzed under North Carolina law, another federal court determined that, in the medical device context, neither privity nor representations made directly to the patient were required under Virginia law. Instead, reasonable anticipation (that the patient would be the end user and could be harmed by a faulty medical device) was all that was required. *Harter v. Ethicon, Inc.*, No. 2:12-CV-00737, 2016 WL 7407425, at *5 (S.D.W. Va. Dec. 15, 2016). However, unlike North Carolina law, Virginia law has a much broader statutory privity exception that extends beyond just a buyer’s household to all person’s “whom the manufacturer or seller might reasonably have expected to use, consume, or be affected by the goods.” *Id.* (citing VA. CODE ANN. § 8.2-

318). Other states, like Arizona¹, California², Georgia³, Florida⁴, and Indiana⁵, tend to require some type of representation of the manufacturer aimed at the patient, which the patient relies on, rather than just a representation made directly to the doctor.

The M&R addressed two district court cases that allowed breach of warranty claims to proceed under North Carolina law, distinguishing the present case from the two district court cases based on the intentionality of the implanted device.

They involve breach of express warranty claims involving devices that were implanted in patients, whereas the drill at issue was not meant to be implanted. . . . Plaintiff [thus] alleges she relied on her doctor's medical judgment in deciding to undergo the surgery, whereas the plaintiff in Resendez and Justus relied on their doctors' judgment in deciding to have the devices implanted.

(DE 15 at 5–6) (internal citation omitted). While Defendant agrees the warranty claims should be dismissed, it objects to the M&R's intentionality dichotomy, arguing this is irrelevant and would improperly expand privity exceptions under North Carolina law to include unintentionally implanted medical devices, just as the *Resendez* and *Justus* federal district courts improperly expanded North Carolina's privity exceptions for intentionally implanted medical devices.

Here, Plaintiff's breach of warranty claims fail for lack of privity.⁶ It is undisputed that

¹ *Hix v. Bos. Sci. Corp.*, No. CV-19-00422-PHX-DJH, 2019 WL 6003456, at *6 (D. Ariz. Nov. 14, 2019) (“[P]rivacy may exist between the patient and the manufacturer and a breach of express warranty could be brought, if the plaintiff was capable of pleading sufficient facts to show that the manufacturer made representations specifically to the plaintiff, rather than just plaintiff's physicians.”) (internal citations omitted).

² *Zetz v. Bos. Sci. Corp.*, 398 F. Supp. 3d 700, 710 (E.D. Cal. 2019) (“[I]n the context of implantable medical products, privity does not exist between the patient and the manufacturer if the patient did not rely on the manufacturer's judgment but did rely on the physician's skill and judgment.”)

³ *Andrews v. RAM Med., Inc.*, No. 7:11-CV-147 HL, 2012 WL 1358495, at *3 (M.D. Ga. Apr. 19, 2012) (holding that breach of warranty claims fail for lack of privity “because the surgical mesh was not sold directly to Plaintiffs”) (citing *Gowen v. Cady*, 189 Ga. App. 473 (1988)).

⁴ *Humleker v. Bos. Sci. Corp.*, No. 619CV1210RL31EJK, 2019 WL 6465059, at *2 (M.D. Fla. Dec. 2, 2019) (Privity is required, but a plaintiff may meet a “relaxed” privity standard if it “relied on the safety claims in those advertisements” of the defendant manufacturer purposely targeting patients like the plaintiff.).

⁵ *Bayer Corp. v. Leach*, 153 N.E.3d 1168, 1190 (Ind. Ct. App. 2020) (privity is not required when the manufacturer made warranties directly to remote purchaser).

⁶ The Court does not address the intentionally aspect of the implanted medical device as the warranty claims fail for lack of privity.

Plaintiff did not buy the drill bit from Defendant. Thus, to maintain her breach of warranty claims, one of the exceptions to the privity requirement must apply. The first statutory exception, which is under North Carolina's version of the Uniform Commercial Code, removes the privity requirement in personal injury cases for express or implied warranties where the injured party is a "natural person who is in the family or household of his buyer or who is a guest in his home if it is reasonable to expect that such person may use, consume or be affected by the goods." N.C. GEN. STAT. ANN. § 25-2-318. Assuming, *arguendo*, that the doctor or hospital was the buyer of the drill bit, Plaintiff is not a family member or guest in the household of the doctor or hospital. Thus, this exception does not apply.

The second statutory exception, which is under the North Carolina Products Liability Act, removes the privity requirement for "a buyer, as defined in the Uniform Commercial Code, of the product involved" in bringing "a product liability action directly against the manufacturer of the product involved for breach of implied warranty." N.C. GEN. STAT. ANN. § 99B-2. Under North Carolina's Uniform Commercial Code, a buyer is "a person who buys or contracts to buy goods." N.C. GEN. STAT. § 25-2-103(1)(a). "Goods" include "all things (including specially manufactured goods) which are movable at the time of identification to the contract for sale." *Id.* § 25-2-105(a). Here, Plaintiff did not buy the drill bit from her doctor, nor did she contract to buy the drill bit. This negates the second privity exception as Plaintiff was not a buyer. Moreover, Defendant made no representations aimed at Plaintiff regarding the drill bit, and Plaintiff did not elect to undergo the surgery because of any representations made by Defendant. This case is, therefore, not akin to *Kinlaw* and *Alberti* where North Carolina courts allowed breach of implied warranty claims to proceed where the manufacturers made representations aimed at the ultimate buyer.

Instead, like most patients, Plaintiff's sole reliance was on the medical judgment of her

doctor, rather than the tools her doctor was using. (DE 8 at ¶35) (“In determining whether to undergo the left hip arthroscopic labral repair and femoroplasty, Plaintiff reasonably relied upon the medical judgment of Dr. Weeks.”). While other cases have found that any alleged affirmations made to the doctor can inure to the benefit of the patient through an agency analysis, this is outside the current legal framework, and the Court declines to stretch the narrow privity exceptions. Accordingly, Plaintiff’s warranty claims fail for lack of privity as no exception applies.


IV. CONCLUSION

IT IS, THEREFORE, ORDERED that:

1. The M&R, (DE 15), is **ADOPTED**;
2. Defendant’s Motion to Dismiss Plaintiff’s Amended Complaint, (DE 11), is **GRANTED in part** and **DENIED in part**. Specifically, it is **GRANTED** as to the warranty claims and **DENIED** as to the negligence claim.

SO ORDERED.

Signed: August 10, 2022


Robert J. Conrad, Jr.
United States District Judge

